

### **REMARKS**

The Office Action of December 30, 2003 has been reviewed and its contents carefully noted. Reconsideration of this case is earnestly requested. Claims 1-46 remain in this case, claims 1, 4, 42 and 43 being amended by this response. Claims 4 and 42 are amended to correct obvious typographical errors. The amendment of claims 1 and 43 is supported throughout the specification, and particularly at page 1, line 15 and page 2, line 18; no new matter has been added.

The Examiner's attention is drawn to the fact that submitted herewith is Applicant's Declaration of Dr. Kennie U. Dee, Ph.D., under 37 C.F. R. § 1.132, attesting to certain facts in support of Applicant's response to the Office Action. The Examiner's consideration of Applicant's Declaration is respectfully requested.

A Petition and fee for extension of time under 37 CFR § 1.136 also accompany this Amendment.

#### **Restriction/Election Requirement**

Applicant gratefully acknowledges Examiner's statement that the requirement for election of species has been withdrawn, and that all claims are examined on the merits.

#### **Allowable Subject Matter**

Applicant gratefully acknowledges Examiner's statement that claims 35-42 are allowed.

Claims 21, 25, 27 and 34 were objected to as being dependent upon a rejected base claim, but the Examiner indicated that they would be allowable, if rewritten in independent form, including all of the limitations of the base claim and any intervening claims.

Applicant gratefully acknowledges Examiner's statement that claims 21, 25, 27 and 34 are allowable. However, Applicant defers amendment at this time, as the rejection of independent claim 1, from which claims 21, 25, 27 and 34 depend, is hereby respectfully traversed (see arguments below and attached Declaration of Dr. Kennie U. Dee, Ph.D.).

It is respectfully submitted that the objection is thus overcome. Reconsideration and withdrawal of the objection to claims 21, 25, 27 and 34 are therefore earnestly requested.

**Rejection under 35 U.S.C. § 102**

Claims 1-4, 7-8, 10-11, 13, 15-19, 22-24, 26, 28-33 and 43-46 were rejected under 35 U.S.C. § 102(b) as being anticipated by White (US 5,431,916). Applicant respectfully disagrees with the rejection.

Applicant's original independent claim 1 recites, *inter alia*, a liquid pharmaceutical composition, and original independent claim 43 recites, *inter alia*, a method for preparing a taste-masked liquid pharmaceutical composition. White does not disclose such a composition or a method for preparing it. Rather, the pharmaceutical compositions disclosed by White are encapsulated and thus are not administered in liquid form. Indeed, all of the examples disclosed by White are compositions and methods for manufacture of pharmaceuticals that are encapsulated within soft gelatin capsules. Therefore, White does not disclose each and every limitation of Applicant's independent claims 1 and 43, and thus the reference cannot anticipate the claims. It is respectfully submitted that the rejection of claims 1 and 43 as being anticipated by White is thus overcome. Reconsideration and withdrawal of the rejection are therefore earnestly requested.

Although Applicant disagrees with the rejection, in order to advance the prosecution of this application and to further clarify the claim language, independent claims 1 and 43 are hereby amended to expressly recite that the claimed taste-masked liquid pharmaceutical composition is administered in liquid form. Such amendment is not deemed to narrow the scope of the claims, because the original claims already recited a liquid pharmaceutical composition, which one of ordinary skill in the art would understand is administered in liquid form. Furthermore, White's composition is a solid at room temperature, and a bitter-tasting solid at that, thus White does not disclose a liquid composition or the taste-masking thereof. See Declaration of Dr. Kennie U. Dee, Ph.D. (particularly Exhibit 2).

It is respectfully submitted that the rejection is overcome by the amendment of claims 1 and 43, and further by Applicant's Declaration of Dr. Kennie U. Dee, Ph.D. (attached hereto). Reconsideration and withdrawal of the rejection are therefore earnestly requested.

Dependent claims 2-4, 7-8, 10-11, 13, 15-19, 22-24, 26, 28-33 and 44-46, being dependent upon and further limiting independent claims 1 and 43, should be allowable for that reason, as well as for the additional limitations recited therein. Reconsideration and withdrawal of the rejection of claims 1-4, 7-8, 10-11, 13, 15-19, 22-24, 26, 28-33 and 43-46 as being anticipated by White are respectfully requested.

### Rejections under 35 U.S.C. § 103

Claims 5, 6, 9, 12, 14 and 20 were rejected under 35 U.S.C. § 103(a) as being obvious over White (US 5,431,916).

Applicant respectfully disagrees, and maintains that the claims, as amended, are patentable over White, for the reasons given above in respect to the section 102 rejection of independent claim 1, from which claims 5, 6, 9, 12, 14 and 20 depend, as shown by Applicant's Declaration of Dr. Kennie U. Dee, Ph.D. (attached hereto). The arguments above as to the novelty of claim 1 are repeated here by reference. It is respectfully submitted that the rejection is thus overcome. Reconsideration and withdrawal of the rejection of claims 5, 6, 9, 12, 14 and 20 as being obvious over White are respectfully requested.

Further, there is no teaching in the prior art of record that one of ordinary skill in the art would be motivated to modify White, or would have a reasonable expectation of success in modifying White, as suggested by the Examiner. See attached Declaration of Dr. Kennie U. Dee, Ph.D.

Applicant's invention addresses the problem of the unpleasant taste of a drug in a liquid format, where the liquid composition is a syrup, a ready-to-use suspension, or extemporaneously prepared liquid syrup or suspension such as, for example, dry powder for reconstitution with water, liquid concentrate for dilution, dispersible tablet or capsule. Specification at page 3, lines 14-17. The taste-masked liquid composition has substantially reduced bitter taste and aftertaste. Specification at page 3, line 3. White's invention, on the other hand, is "a pharmaceutical **encapsulated** composition" (see, e.g., claims 1-19). Indeed, all of the examples disclosed by White are compositions and methods for manufacture of pharmaceuticals that are encapsulated within soft gelatin capsules, and thus are **not administered in liquid form**. Thus, White provides a solution to a different problem, which is that of solubility.

Furthermore, White's composition is a solid at room temperature, and a bitter-tasting solid at that, thus White does not teach or suggest a liquid composition or the taste-masking thereof. See Declaration of Dr. Kennie U. Dee, Ph.D. (particularly Exhibit 2).

Moreover, White provides absolutely no teaching whatsoever regarding a taste-masked liquid pharmaceutical composition or a method for making the same. For example, White teaches that polyethylene glycol may be used to solubilize certain pharmaceutical actives (column 6, lines 41-42), stating that polyethylene glycol **may be employed to facilitate the solubility of actives or modify the viscosity of suspensions** (column 7, lines 24-30). However,

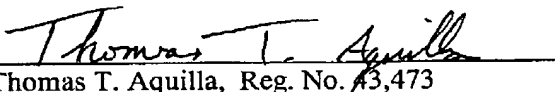
the reference does not teach the use of polyethylene glycol to create a taste-masking effect in a liquid pharmaceutical composition. Indeed, White does not provide any teaching regarding the taste-masking effect of the embodiments disclosed therein. While brief mention is made of the suitability of the compositions for oral administration, there is absolutely no teaching regarding a taste-masking effect and/or taste acceptability of the preparations. Similarly, White discloses that polyvinylpyrrolidone is a **solubilizing or a suspending agent** in combination with the tri-ester, however, the reference provides no teaching that polyvinylpyrrolidone should be used to create a taste-masking effect in a liquid pharmaceutical composition. Thus, White does not teach or suggest Applicant's invention as recited in claim 1.

Dependent claims 5, 6, 9, 12, 14 and 20, being dependent upon and further limiting independent claim 1, should be allowable for that reason, as well as for the additional limitations recited therein. Reconsideration and withdrawal of the rejection of claims 5, 6, 9, 12, 14 and 20 as being obvious over White are therefore respectfully requested.

Applicant believes the claims are patentable over the prior art, and that this case is in condition for allowance of all claims therein. Such action is thus respectfully requested. If the Examiner disagrees, or believes for any other reason that direct contact with Applicant's attorney would advance the prosecution of the case to finality, he is invited to telephone the undersigned at the number given below.

"Recognizing that Internet communications are not secured, I hereby authorize the PTO to communicate with me concerning any subject matter of this application by electronic mail. I understand that a copy of these communications will be made of record in the application file."

Respectfully Submitted:  
Santos *et al.*

By:   
Thomas T. Aquilla, Reg. No. 43,473  
Attorney for Applicant  
Brown & Michaels, PC  
400 M&T Bank Building - 118 North Tioga Street  
Ithaca, New York 14850  
(607) 256-2000 • (607) 256-3628 (fax)  
e-mail: aquilla@bpmlegal.com

Dated: April 22, 2004